

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR
ENTRY OF QUALIFIED PROTECTIVE ORDER
FOR PROTECTED HEALTH INFORMATION**

I. INTRODUCTION

Plaintiffs, through the Plaintiffs' Steering Committee ("PSC"), move this Court for entry of a qualified protective order under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 1-4-191, regulations adopted thereto (see 45 C.F.R. § 164.501, et seq.), and similar state laws in order to protect the information sought by the issuance of subpoenas to hospitals, pharmacies, and clinics.

The PSC consulted with the Chapter 11 Trustee, the Official Creditors Committee ("OCC") and their counsel, counsel for New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (NECC), Ameridose LLC, Medical Sales Management, Inc., Doug Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Conigliaro Cadden, Glenn Chin, (collectively, the "Affiliated Defendants") and understand that they do not oppose entry of the proposed order. The PSC also made their best efforts to send the proposed order to all other defense counsel for their comments. The PSC had not received any objections to the attached proposed qualified protective order as of the time of this filing.

II. A QUALIFIED PROTECTIVE ORDER SHOULD BE ENTERED TO GOVERN ANY PROTECTED HEALTH INFORMATION PRODUCED IN THIS MDL.

A. The proposed Qualified Protective Order covers protected health information.

The PSC will, imminently, begin serving subpoenas on healthcare providers identified by the Centers for Disease Control and Prevention (CDC) who received lots of methylprednisolone acetate (PF) recalled from New England Compounding Center on September 26, 2012. These subpoenas will ask these healthcare providers to identify patients who received NECC products by name. (These initial subpoenas will not ask for medical records.)

This information is critical to identifying potential claimants in this MDL and Bankruptcy Actions to provide notice of potential claims against NECC, its affiliated entities, and other potential defendants. It is also important to establishing liability of various Defendants – if, for example, prescription records reflect that a pain clinic identified “Donald Duck” as a patient.

The PSC requests that the Court issue a qualified protective order under HIPAA, imposing the following conditions on the production and use of protected health information by subpoena recipients:

- a. All protected health information produced pursuant to a subpoena shall be produced only to a third party vendor (the “Vendor”)¹ selected jointly by Plaintiffs’ Steering Committee, the chapter 11 trustee appointed in NECC’s chapter 11 case (the “Trustee”), and the Official Committee of Unsecured Creditors appointed in NECC’s chapter 11 case (the “Official Committee”);
- b. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court;
- c. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in

¹ The PSC, along with the Creditors’ Committee, solicited proposals for HIPAA compliant vendors. We are in the process of meeting and conferring with other parties to select a vendor. We will notify the Court and subpoena recipients once the vendor has been selected.

electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

- d. The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose.
- e. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.
- f. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

The proposed qualified protective order provides that the protected information will be provided to a vendor, not plaintiffs' counsel. The order also provides that the protected health information may not be used for any purpose without further order from the Court.

The PSC also requests that the Court order that all subpoenaed entities that provide requested information fall within the safe harbor of HIPAA for court-ordered production of personal health information, 45 C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state statute, regulation, or other requirement, for supplying patient or member information to the Vendor.

Finally, the PSC requests that the Court order that the Vendor shall not be deemed to be a guarantor of the completeness and accuracy of the data provided to it and shall have the right to rely in good faith upon the information provided by the subpoenaed entity.

A proposed Qualified Protective Order is attached as Exhibit A.

B. The proposed Qualified Protective Order does not limit a subpoena recipient's ability to object to producing protected health information.

The attached proposed order addresses only how protected health information will be produced, if any such information is produced, during discovery.

The proposed order does not restrict in any way, shape, or form a subpoena recipient's ability to object to a subpoena requesting protected healthcare information, the scope of the protected information sought, or the time constraints imposed by the subpoena. A subpoena recipient may raise any and all legally cognizable objections to the request to produce protected health information that are available to a subpoena recipient.

The PSC will separately move the Court to enter an order that confirms that it will centrally enforce subpoenas issued out of the MDL and that objections to subpoenas should be filed directly with this Court. The Court will hear argument on any objections to the PSC's subpoenas during the July 18, 2013 MDL status conference.

C. Courts regularly enter orders governing the production of protected health information for notice and claims administration purposes.

The names and addresses of patients, along with the specific NECP product prescribed by these clinics constitutes "Protected Health Information" within the meaning of HIPAA, regulations adopted thereto (*see* 45 C.F.R. § 164.501, et seq.), and related state laws. HIPAA protects the confidentiality of Protected Health Information but provides mechanisms for disclosure of such information when necessary and if sufficiently protected from improper use. *See* 45 C.F.R.

§ 164.502(a). In particular, HIPAA regulations allow for release of information if the request is made through or pursuant to a court order. *See* 45 C.F.R. § 164.512(e)(1)(i).

A subpoena may be issued to compel the disclosure of Protected Health Information so long as a “qualified protective order” is issued prohibiting “the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested.” 45 C.F.R. § 164.512(e)(1)(v)(A). The “qualified protective order” must require the return or destruction of the information at the end of the litigation. *See* 45 C.F.R. § 164.512(e)(1)(ii); *Northwestern Mem'l Hosp. v. Ashcroft*, 362 F.3d 923 (7th Cir. 2004).

Courts routinely enter qualified protective orders to safeguard the confidentiality of protected health information. In this district alone, courts have entered at least six orders that permitted the production of protected health information to an independent vendor for purposes of notice and claims administration:

- *Commonwealth Care Alliance v. AstraZeneca Pharmaceuticals L.P.*, 05-0269-BLS, Dkt. No. 169 (Suffolk Sup. Dec. 20, 2012) (Sanders, J.);
- *In re Relafen Antitrust Litig. v. Smithkline Beecham Corp.*, 2004 U.S. Dist. LEXIS 29834, at *17-18 (D. Mass. Nov. 24, 2004) (Young, J.);
- *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 01-CV-12257-PBS, Dkt. No. 5455 (D. Mass. July 21, 2008) (Saris, J.);
- *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 01-CV-12257-PBS, Dkt. No. 865 (D. Mass. June 8, 2004) (Saris, J.);
- *Government Employees Hosp. Ass'n v. Serono Int'l S.A.*, 05-cv-11935-PBS, Dkt. No. 109 (D. Mass. July 13, 2007) (Saris, J.); and
- *New England Carpenters Health Benefits Fund v. First Databank, Inc.*, 05-cv-11148-PBS, Dkt. No. 139 (D. Mass. 2006) (Saris, J.).

Courts in other jurisdictions have entered similar orders addressing the production of protected health information:²

- *In re Visa Check/Mastermoney Antitrust Litig.*, 2002 U.S. Dist. LEXIS 23327, at *6-7 (E.D.N.Y. June 21, 2002);
- *Mercier v. Courtyard Nursing Care Ctr.*, 25 Mass. L. Rep. 461 (Mass. Super. Ct. 2009);
- *In re Bextra and Celebrex Marketing, Sales Practices and Prod. Liab. Litig.*, 05-CV-01699-CRB, Dkt. No. 2595 (N.D. Cal. Dec. 8, 2008) (Breyer, J.);
- *Commonwealth of Virginia v. McKesson Corporation*, 11-02782-SI, Dkt. No. 31 (N.D. Cal. Dec. 12, 2011) (Illston, J.);
- *In re Tricor Indirect Purchaser Antitrust Litig.*, 05-cv-00360-SLR, Dkt. No. 510 (D. Del. May 8, 2009) (Robinson, J.);
- *In re Tricor Indirect Purchaser Antitrust Litig.*, 05-cv-00360-SLR, Dkt. No. 558 (D. Del. Feb. 2, 2010) (Robinson, J.);
- *In re Actiq Sales and Mktg. Practices Litig.*, 07-cv-04492-PBT, Dkt. No. 293 (E.D. Penn. Sept. 7, 2011) (Tucker, J.).

III. CONCLUSION

The Plaintiffs' Steering Committee respectfully request that the Court grant this Motion and enter the qualified protective order attached hereto, and grant such other and further relief as this Court deems appropriate.

Dated: June 13, 2013

/s/ Kristen Johnson Parker

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² See also 247 CMR 9.01(19).

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Kristen Johnson Parker, hereby certify that I caused a copy of the foregoing motion for entry of qualified protective order, memorandum in support, and proposed order to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: June 13, 2013

/s/ Kristen Johnson Parker
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